



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,178	09/30/2003	Marco Pinna	243129US0	1258

22850 7590 09/11/2006

C. IRVIN MCCLELLAND
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,178

Applicant(s)

PINNA ET AL.

Examiner

Susan E. Fernandez

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/04, 2/25/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6, in the reply filed on April 26, 2006, is acknowledged. The traversal is on the ground(s) that there is a commonality (technical relationship) that exists between the composition of Group I, and the method of making the composition of Group I, and which defines the contribution which each of the groups taken as a whole makes over the prior art. This is not found persuasive because the inclusion of multiple inventions in the examination of an application wherein the inventions are so linked as to form a single general inventive concept is appropriate restriction practice only for international applications or national stage applications filed under the Patent Cooperation Treaty. Additionally, applicant asserts that the Office has failed to show that a burden exists in searching all the claims. However, Xu et al. (US 6,419,903) serves as an example of a prior art reference which teaches the composition of claim 1 (abstract), but does not teach the method of claim 7. Clearly, this demonstrates that the claimed product can be made by a different process. In conclusion, the requirement is still deemed proper and is therefore made FINAL.

Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-6 are examined on the merits to the extent they read on the elected subject matter.

Claim Objections

Claim 1 is objected to because of the following informalities: The last two lines of the claim recite “quantity exceeding 10% on the total film weight,” which is grammatically incorrect. It is suggested that “on” following “10%” be replaced with “of.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the recitation “quick water-dissolving film” since it is unclear what aspect of the film is considered “quick.” It is not clear whether the time/rate by which the film dissolves in water is considered “quick.” Moreover, it is not clear what times/rates would be considered “quick.” Claim 1 is indefinite also because it is unclear what is defined by “at least one cellulose compatible with said starch.” It is unclear what characteristics the cellulose(s) must have in order to be considered “compatible” with the starch, thus it is unclear what celluloses would be encompassed by the above recitation. Additionally, “said starch” in this recitation lacks antecedent basis. It is suggested that “said starch” be replaced with “said at least one starch.” Finally, “at least one cosmetic, aromatic, pharmaceutical and/or food substance” is confusing. It is not clear that this recitation is referring to at least one

Art Unit: 1651

cosmetic substance, aromatic substance, pharmaceutical substance and/or food substance. Thus, claims 1-6 are rejected under 35 U.S.C. 112, second paragraph.

Claim 2 is confusing since it is unclear whether “probiotic, prebiotic and symbiotic food bacteria” refers to probiotic food bacteria, prebiotic food bacteria, and symbiotic food bacteria. Thus, claims 2, 3, 5, and 6 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US 6,419,903).

Xu et al. discloses a “rapidly dissolvable orally consumable film composition” comprising “water soluble, low viscosity hydroxyalkylmethyl cellulose and water dispersible starch and a flavoring agent” (abstract). The flavoring agent can be considered a cosmetic, aromatic, pharmaceutical and/or food substance. Moreover, this flavoring agent is present in the film composition in an amount ranging “from about 2.0 to about 10% by weight” (column 4, lines 3-6). Given that “about 10%” embodies percentages above 10%, such as 10.1%, the Xu invention clearly anticipates instant claim 1. Additionally, Xu et al. teaches instant claim 4, since the hydroxyalkylmethyl cellulose may be hydroxypropyl methyl cellulose (claim 2). A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely et al. (US 5,716,615).

Cavaliere Vesely et al. discloses a pharmaceutical composition containing several different bacteria, including *Streptococcus thermophilus* and lactobacilli (lactic bacteria) and bifidobacteria (abstract). The bacteria in the composition, which is considered a pharmaceutical/food substance as the Cavaliere Vesely invention is a dietary and pharmaceutical composition for treating gastrointestinal disorders and potentiating a host's immune system (column 2, lines 12-20), is preferably present in an amount of from 5% to 85% by weight of the

Art Unit: 1651

composition (column 2, lines 52-55). Thus, Cavaliere Vesely et al. teaches the food substance requirements recited in instant claim 1, and the limitations recited in instant claims 2 and 3. Additionally, the pharmaceutical composition disclosed in the reference further comprises a pharmaceutically acceptable excipient (claim 1), and preferred excipients include microcrystalline cellulose and maize starch (column 3, lines 37-40).

Cavaliere Vesely et al. differs from the claimed invention in that it does not expressly disclose that the pharmaceutical composition is a “quick water-dissolving film.” Nevertheless, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have prepared the composition of Cavaliere Vesely et al. in the form of a film. One of ordinary skill in the art would have been motivated to do this since the Cavaliere Vesely composition “...can be made in conventional pharmaceutical forms, such as for example...suppositories...” (column 3, lines 19-22). Since a film is considered a conventional pharmaceutical form and a form suitable for a suppository, the artisan of ordinary skill in the art would have recognized the suitability of the film form as an alternative form of the Cavaliere Vesely invention. Since there is uptake of the Cavaliere Veseley et al. composition, the composition is considered “water-dissolving.” A holding of obviousness is clearly required.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely et al. as applied to claims 1-3 above, and further in view of Xu et al. (US 6,419,903) or Sharik (US 5,206,026).

Art Unit: 1651

As discussed above, Cavaliere Vesely et al. render claims 1-3 obvious. However, the reference does not expressly disclose that the cellulose in the Cavaliere Vesely composition is a hydroxypropylmethyl cellulose or a hydroxyethyl cellulose.

Xu et al. discloses a “rapidly dissolvable orally consumable film composition” comprising “water soluble, low viscosity hydroxyalkylmethyl cellulose and water dispersible starch and a flavoring agent” (abstract). Additionally, the hydroxyalkylmethyl cellulose may be hydroxypropyl methyl cellulose (claim 2).

Sharik discloses an instantaneous delivery film for the delivery of a therapeutic agent (abstract), wherein the delivery film comprises of a film-forming polymer which must be water soluble (column 3, lines 15-17). Suitable film-forming polymers include hydroxyethyl cellulose.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Cavaliere Vesely invention such that hydroxypropyl methyl cellulose or hydroxyethyl cellulose is used as the cellulose of the Cavaliere Vesely invention. One of ordinary skill in the art would have been motivated to do this since these two celluloses would have enabled the formation of a film. Thus, a holding of obviousness is clearly required.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Hata (US 4,345,032) and Sharik.

As discussed above, Xu et al. anticipates claims 1 and 4. However, Xu et al. does not expressly disclose that bacteria is present in the disclosed composition.

Hata discloses that specific lactobacillus strains have the ability to deodorize foul breath (column 1, lines 42-45).

Art Unit: 1651

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the flavoring agent of the Xu invention with specific lactobacillus strains appropriate for deodorizing foul breath. One of ordinary skill in the art would have been motivated to do this since these lactobacillus strains would have served as breath freshening agents, as required by the Xu invention.

Xu et al. also differs from the instant invention in that it does not teach a composition comprising hydroxyethyl cellulose.

Sharik discloses an instantaneous delivery film for the delivery of a therapeutic agent (abstract), wherein the delivery film comprises of a film-forming polymer which must be water soluble (column 3, lines 15-17). Suitable film-forming polymers include hydroxyethyl cellulose.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Xu invention such that hydroxyethyl cellulose is used as the cellulose of the Xu invention. One of ordinary skill in the art would have been motivated to do this since this cellulose would have enabled the formation of a film. Thus, a holding of obviousness is clearly required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Art Unit: 1651

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/680,115.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a film comprising a cellulose, a starch, and bacteria, which are encompassed by the copending claims which also may comprise of these same components in one composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444.

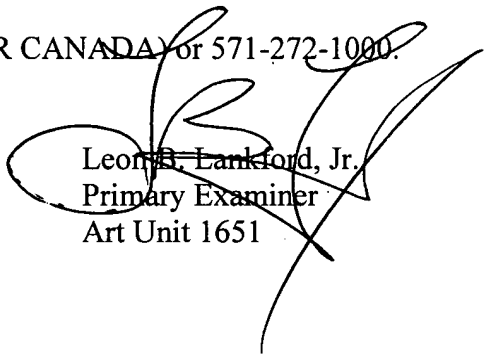
The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

sef



LIST OF RELATED CASES

	<u>Docket Number</u>	<u>Serial or Patent Number</u>	<u>Filing or Issue Date</u>	<u>Inventor/ Applicant</u>
SF	243673US0	10/680,115	10/08/03	PINNA, et al.
SF	243129US0*	10/673,178	09/30/03	PINNA, et al.

/Susan Fernandez/

09/05/2006

*Present Application; listed for information
NFO/amr